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November 5, 2019

VIA ECF
Honorable Joel Schneider
United States Magistrate Judge
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, New Jersey 08101

Re: IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Schneider:

This initial letter is submitted on behalf of the Plaintiffs with regard to the macro discovery issues identified in the Court's Order directing this briefing.

LEGAL STANDARD

The Federal Rules provide for broad and liberal discovery. *In re Madden*, 151 F.3d 125, 138 (3d Cir. 1998) ("Pretrial discovery is….accorded a broad and liberal treatment.") (internal quotations and citation omitted); Wright, Miller & Marcus, Federal Practice & Procedure, Civil 2d § 2007 ("The rule does allow broad scope to discovery and this has been well recognized by the courts."). Rule 26(b)(1) provides that "[p]arties may obtain discovery regarding any

nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b) (amended effective Dec. 1, 2015). "Information within this scope of discovery need not be admissible in evidence to be discoverable." *Id.*[1] The resisting party bears the burden of establishing lack of relevance, undue burden, or some other appropriate basis. *See, e.g.*, *Fattone v. Burger*, Civ. A. No. 2:12-cv-1691, 2015 WL 4608061, at *2-3 (W.D. Pa. July 31, 2015) (Ex. 1).[2] A resisting party or non-party must clearly demonstrate the basis for withholding the discovery; generalized allegations or speculation will not satisfy this burden. *See, e.g.*, *Josephs v. Harris Corp.*, 677 F.2d 985, 992 (3d Cir. 1982) ("Mere recitation of the familiar litany that an interrogatory or a document production request is overly broad, burdensome, oppressive and irrelevant will not suffice."); *Fattone*, 2015 WL 4608061, at *3.

ARGUMENT

I. Defendants' Boilerplate Objections Must be Stricken

On August 31, 2019, Plaintiffs served one set of comprehensive discovery requests on all API and Finished Dose Manufacturer Defendants (hereafter, "Defendants"), addressing a comprehensive, but reasonable and expected, set of topics, including: organizational information, regulatory communications, testing, manufacturing processes, complaints, sales, distribution, and pricing. Defendants responded with over 400 pages of objections, largely mirroring one another with minor differences, including pages upon pages of perfunctory general objections. These general objections were then incorporated by reference into each of the Defendants' specific

[1] The 2015 amendments to the Federal Rules did not alter this "clear focus" of Rule 26(b), which has been the same and in effect since the 1983 revisions to the rule. *See* Fed. R. Civ. 26(b) advisory comm. notes (2015).
[2] All exhibits are attached hereto unless otherwise noted.

responses. *See* Ex. 2, Mylan's Objections to Plaintiffs' RFPDs ("Mylan's Objs. to RFPDs") at 2-7 as an example. Perhaps most important, the responses included **no commitment to producing any small sub-section of obviously non-objectionable documents beyond that which was produced in Core Discovery**. In fact, the most Defendants would commit to was a *willingness* to "engage in a meet-and-confer."[3] *Id.*

This Court has repeatedly cautioned that boilerplate objections are unacceptable. Boilerplate, generalized objections are inadequate and are tantamount to making no objection at all. *Walker v. Lakewood Condo Owners Ass'n*, 186 F.R.D. 584, 587 (C.D. Cal. 1999). To remove any doubt, Rule 34 was revised in 2015 to make clear that Rule 34 objections must be stated with

[3] Defendant Aurolife has agreed to produce the ANDA application for one of their Valsartan products, which was not previously produce in Core Discovery. Defendant Teva has agreed to produce unredacted versions of emails produced in core discovery when it eventually produces documents from the custodial file of an agreed-upon Teva custodian. On November 5, 2019, the Manufacturing Defendants emailed Plaintiffs the following:

> During our meet and confer yesterday regarding the macro discovery issues, Plaintiffs proposed that the Manufacturing Defendants should agree to amend their objections to Plaintiffs' document requests in light of Plaintiffs' assertion that the Manufacturing Defendants have asserted "boilerplate" objections in response to each document request. The Manufacturing Defendants disagree with that characterization, as many of their objections are explicitly tied to the drug at issue and the alleged impurities, manufacturing processes, and injuries at issue, and because many of the objections are subject to the resolution of macro discovery issues. Nevertheless, the Manufacturing Defendants will be amending their objections to the document requests, and intend to provide Plaintiffs with an amended set of objections on or before November 13.

(Ex. 28). However, Plaintiffs have no idea of the extent or content of the modifications they propose, and have little confidence that they will remedy the full scope of the improper objections, as discussed *infra*.

specificity, including a statement as to whether any responsive materials are being withheld on the basis of that objection. If an objection is made as to overbreadth in part, the objection must also state the scope of the request that is not overbroad. *See* Rule 34, 2015, Advisory Committee Notes.

Yet despite these clear admonitions, Defendants ZHP, Teva, Mylan, Aurobindo and Torrent[4] each list 27 or more general objections. These general objections are then incorporated in the response to each individual objection as if fully set forth therein. "[I]ncorporating all of the General Objections into each response violates Rule 34 (b)(2)(B)'s specificity requirements as well as Rule 34 (b)(2)(C)'s requirement to indicate whether any responsive materials are withheld on the basis of an objection. General objections should be rarely used after December 1, 2015 unless each such objection applies to each document request (e.g., objecting to produce privilege material)." *Fisher v. Forrest*, No. 14 Civ. 1304, 2017 WL 773694, at *3 (S.D.N.Y. Feb, 28, 2017) (Ex. 5). Instead, the objecting party must articulate the particular harm that would accrue if required to respond to the request. *See St. Paul Reins. Co. Ltd. v. Commercial Fin. Corp*., 198 F.R.D. 508, 511-12 (N.D. Iowa 2000).

Defendants' individual objections are similarly invalid. They frequently object to the requests as overbroad, unduly burdensome, and not proportional to the needs of the action. Many of these objections are nearly identical to specific examples of unacceptable boilerplate

[4] In a letter served when the responses were due, Defendant Hetero USA stated that it was not providing formal responses or objections to discovery because "Hetero USA is not a manufacturing defendant and is merely a FDA liaison." *See* October 15, 2019 Letter from Janet Poletto at Ex. 3. Defendant Camber, for their part, did not respond at all on the October 15th deadline as Camber maintains that it is solely a distributor. Ex. 4 at 2-3, Grossman email to Plaintiffs. The Plaintiffs and Defendant Camber have now begun the process of negotiating discovery. *Id.*

objections given by the courts.[5] With few if any exceptions, Defendants fail to adequately identify the portion of the request that is not overbroad or state what documents are being withheld on the basis of that objection.

Defendants repeatedly object on the basis of vague claims of burden or duplication and weakly refer plaintiffs to the core discovery production. Some objections even state that the term "valsartan" is vague, ambiguous, overly broad and unduly burdensome, lacking in particularity and unreasonable because it does not distinguish between API and finished dose valsartan. At the same time, Defendants themselves use this term throughout their objections. Defendants give very few substantive responses or references to documents. Defendants simply do not have the right to dictate the scope of discovery based on their biased view of the plaintiffs' theories of the case. *Sentis Grp. Inc. v. Shell Oil Co.*, 763 F.3d 919, 925 (8th Cir. 2014).

Defendants' collective obstruction of discovery through this massive wall of objections has set this process back, well behind where it should be after Defendants had 45 days to prepare specific objections. In fact, to the extent the defense had legitimate questions or issues they should have communicated with Plaintiffs to seek agreement on issues that could have been addressed and resolved, and should have identified the requests that would be complied with so that the production process could have begun on a rolling basis with the documents as to which there was no dispute. This strategy simply slows the entire process, and will certainly add to the

[5] *See Liguria Foods, Inc. v. Griffith Laboratories, Inc.* 320 F.R.D. 168, 173-179 (2017) (Objections to the extent it is not limited to a reasonable timeframe and is overly broad and unduly burdensome; objections to the defined term 'Liguria Related Documents' as overly broad; objections to the extent they seek discovery protected by the attorney client privilege; and, objections to the extent they seek disclosure of trade secret or confidential information, are objections listed with strong disfavor). Examples of each can be found in Defendants' requests here.

disputed items left to the Court to resolve. *See Younes v. 7-Eleven, Inc.*, 312 F.R.D. 692, 707 (D.N.J. 2015) (Lawyers should not have to wait until after meet and confer sessions and/or discovery applications or motions to obtain plainly relevant information.).

Perhaps most glaring, even after the Court recently voiced displeasure with general, boilerplate objections, and threatened potential sanctions, no defendant served revised responses deleting obviously improper objections. At this stage it is important for Defendants to understand that their participation in discovery must be in good faith, and they cannot obstruct and delay discovery with impunity.

Defendants' objections should be stricken, and Defendants should be required to state with specificity what documents they intend to produce responsive to each request and what documents they intend to withhold from production. Plaintiffs further request any additional remedies the Court deems appropriate, including sanctions for Defendants' ongoing willful use of clearly improper objections.

II. Plaintiffs Are Entitled to Discovery from Every Entity and Every Manufacturing Facility Involved in the Valsartan Distribution Chain

Plaintiffs have straightforwardly asked Defendants for discovery of every facility with any role for Valsartan[6] – from the facility that manufactures Valsartan API, through testing,

[6] Plaintiffs note that every facility used in the manufacturing, packaging, analytical testing of Valsartan are not only required to be identified in ANDA applications, but are also required to be approved by the FDA for the functions described in the ANDA application. *See* FDA Guidance to Industry on "Good ANDA Submission Practices." This is because, as discussed *infra* at II.a., particular obligations attach at each step. Even Defendants Hetero USA and Prinston, (who both claim to only act as registered US agents for regulatory paperwork purposes), have both been physically inspected by the FDA for the roles and functions they play with respect to the distribution of finished dose product in the United States. Ex. 6, and Ex. 7, EIRs for Prinston and Hetero USA (obtained from Plaintiffs' FOIA requests to the FDA).

packaging, finished dose assembly (e.g., bottling and labeling), and distribution to retailers. Plaintiffs also seek discovery of the entity(ies) that operated or controlled those facilities (to the extent they are different subsidiaries of the named Defendants). Defendants refuse to acknowledge that all such facilities (and any subsidiaries that might operate or control them) must participate in discovery. This is improper. Plaintiffs are entitled to discovery from or relating to all facilities (and entities responsible therefore) involved in valsartan (e.g., valsartan finished dose manufacturing facilities), not just facilities that manufacture valsartan API.

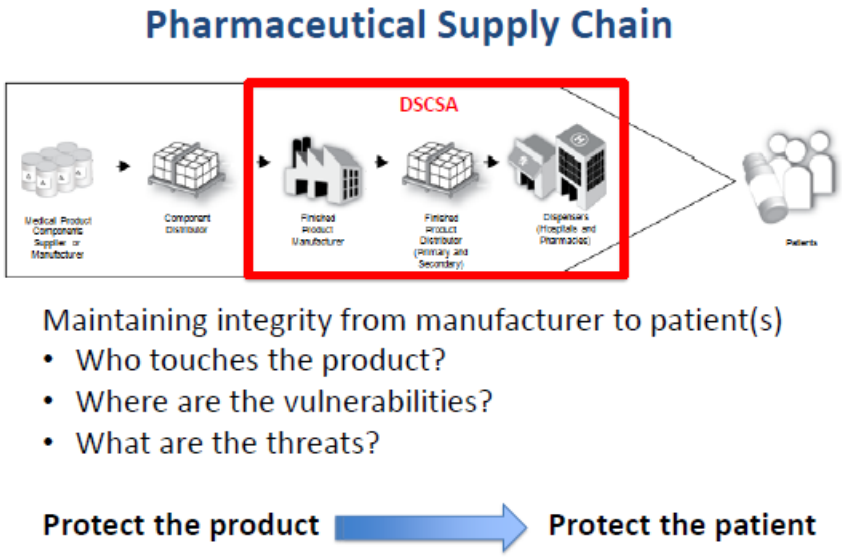
a. All Facilities That Manufactured Valsartan API Must be Subject to Discovery

All of Defendants' facilities that manufactured valsartan API are properly the subject of discovery. However, Defendants have yet to agree to this. There is no good basis, and Defendants have articulated none, for carving out any facilities that manufactured valsartan API. These facilities (and the subsidiaries that may operate or control them) are properly subject to discovery. Many of the Defendants had multiple processes in operation for the manufacture of valsartan API. Defendants have only confirmed they would produce documents from the API Manufacturing facilities for which that API made it into a finished dose pill that was ultimately recalled by the United States Food and Drug Administration. This is simply unacceptable. Additionally, if one facility *did* make contaminated valsartan API and another did not, then the reasons for that are highly pertinent: were the facilities using different manufacturing processes? Different testing methods? Different maintenance processes? This is certainly relevant; at a minimum, it is discoverable.

b. Other Downstream Facilities Should be Subject to Discovery

Discovery cannot be limited *only* to valsartan API manufacturing facilities. Some Defendants appear to take the position that downstream facilities that manufacture Valsartan finished dose, or that bottle or label valsartan finished dose, should be outside the bounds of discovery. This assertion should be rejected for multiple reasons.

First, all downstream facilities (including finished dose, bottling, labeling, and repackaging facilities) each have independent regulatory obligations to prevent adulterated and/or contaminated products from being sold in the United States. *See* The Drug Supply Chain Security Act ("DSCSA"), 21 U.S.C. § 351 *et seq.* The DSCSA affirmatively obligates all parties in the distribution chain to have adequate measures and controls in place to prevent products that are "unfit for distribution" from being distributed. Ex. 8, FDA Presentation re the DSCSA at 9. The below illustration from an FDA presentation of the DSCSA aptly makes this point:



Id. at 10.

Additionally, pursuant to 21 CFR § 211, each step of the manufacturing and distribution chain *also* has independent obligations to comply with current Good Manufacturing Practices ("cGMPs"), including (not only) those entities responsible for API and finished dose manufacture, but also entities responsible for packaging and labeling operations. *See* 21 CFR § 210.3(13). The regulations require all facilities (from API Manufacturing all the way down to labelers and packagers) to comply with obligations concerning quality issues "impacting on the identity and purity of the product" (21 CFR § 211.22) and to have adequate quality controls with respect to "the testing and approval or rejection of….drug products" (*id.*).

As such, every Defendant that had some role in the distribution of valsartan to Plaintiffs should be required to produce discovery, because every Defendant had independent and unique obligations it was required to meet.

i. Finished Dose Manufacturing Facilities

Defendants' own positions are internally inconsistent on whether discovery is appropriate for the finished dose manufacturing facilities. For instance, while Mylan agreed it will produce discovery from or about its valsartan API facilities, it refuses to do so for its two Valsartan finished dose facilities. In contrast, Teva only manufactures valsartan finished dose, but appears to agree that one of its finished dose manufacturing facilities (but not another, an issue discussed *infra*) is a proper subject of discovery. The same is true for other Defendants who are *only* valsartan finished dose manufacturers, such as Torrent and Aurolife. This alone undercuts any individual Defendant's assertion that valsartan finished dose manufacturing facilities should be exempt from discovery.

Moreover, in the wake of the recall, the FDA sent letters to *finished dose* manufacturers reminding them of their obligations to test representative samples of API, as well as testing API lots received from each supplier. Ex. 9 MYLAN-MDL2875-00029792 ("ARB [drug product] manufactures [should] test representative samples of each API batch in their possession to demonstrate the absence of nitrosamines prior to use in [drug product] manufacturing"). Plaintiffs are clearly entitled to discovery from these entities to investigate whether there were out-of-specification test results at the finished dose manufacturing facility for Valsartan (as one such example). Indeed, evidence produced to date suggests that there is a possibility that contamination **could be detected in the finished dose formulations when it was not detected in the API formulation**. Ex. 10, Auro-MDL 2875-0020661 (FDA finding that "API tested negative but [finished dose product] tested positive for NDEA").

1. Mylan

In the years since Mylan began manufacturing finished dose Valsartan products, the two finished dose facilities responsible for manufacturing the Valsartan products were inspected nearly a dozen times, the most recent of which occurred just last year. The collective result of these inspections were two separate warning letters from the FDA (the strongest rebuke possible) for each finished dose manufacturing facility.

At Mylan's Nashik facility, the FDA found that Mylan "failed to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications" and had implemented a quality system that did not "adequately ensure the accuracy and integrity of data to support the safety, effectiveness, and quality of the drugs you manufacture." Ex. 11, April 3, 2017, Mylan Nashik Warning Letter at 2-3. With respect to

Mylan's Morgantown, West Virginia facility, the FDA found that Mylan "failed to follow written procedures for production and process control designed to assure that the drug products you manufacture have the identity, strength, quality, and purity they purport or are represented to possess, and to record and justify any deviations from them (21 CFR 211.100(b))." Ex. 12, November 9, 2018, Morgantown WV Warning Letter at 5.

Notably, Mylan did not produce either of these warning letters in Core Discovery because they were sent to Mylan's valsartan finished dose manufacturing facilities, not its API facilities.[7] In response to subsequent Plaintiffs' RFPDs seeking all inspection information regarding these two specific finished dose manufacturing facilities, Mylan responded that: "MPI…did not manufacture Valsartan API at its Morgantown facility. Accordingly, this Request exceeds the scope of discovery permitted under the Federal Rules of Civil Procedure." Ex. 2, Mylan's Objs. to RFPDs at 95-96.

The relevance of FDA-documented cGMP violations at Mylan's finished dose manufacturing facilities is obvious. Mylan cannot be permitted to escape disclosure of FDA inspection and related documents, which bear upon the company's very compliance with the regulations in place to prevent unsafe contaminated drugs from entering the market. Mylan must

[7] Plaintiffs specifically identified the non-production of these warning letters in documenting obvious deficiencies in Defendants' Core Discovery production. At the time, Mylan reasoned that discussions regarding inspections of these two finished dose manufacturing facilities were premature, and that the "purpose of [the core discovery] meet-and-confer process is to evaluate whether Mylan has produced the documents identified in the Court's core discovery order, not some overarching inquiry of what might be somehow "relevant" in the context of this litigation." Ex. 13, Trischler Letter to Pls at 3. Mylan concluded that, "Mylan was not required to produce Nashik and Morgantown materials ***at this stage***." *Id.* (emphasis added). The stage to produce these documents has now arrived.

be compelled to produce discovery regarding its finished dose manufacturing facilities immediately.

2. ZHP

Like Mylan, ZHP has taken the position that discovery from the Xunqiao facility (which manufactured the valsartan finished dose) is not relevant to any party's claims or defense nor proportional to the needs of the action. This includes all documents related to FDA inspections of the Xunqiao facility. In 2016, FDA inspectors observed that ZHP's Valsartan finished dose manufacturing failed to "establish laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans and test procedures designed to assure that drug products conform to appropriate standards of identify, strength, quality and purity." Ex. 14, November 18, 2016 form 483 at Observation No. 2 (obtained from Plaintiffs' FOIA requests). Plaintiffs are clearly entitled to discover information regarding ZHP's compliance with the cGMPs, including whether ZHP was implementing appropriate specifications, standards, sampling plans and testing procedures in place to assure that Valsartan was not contaminated. These same principles apply across all of the finished dose manufacturers.

3. Teva

Teva concedes that its Valsartan finished dose facility in Jerusalem is within the bounds of discovery. However, it inexplicably claims that another finished dose facility in Malta should not be. This is untenable.

There does not appear to be any dispute that the Malta facility obtained valsartan API from ZHP, and in turn manufactured valsartan finished dose that was sold in the United States. Teva, through acquisition, appears to have obtained the Malta facility, as well as obtaining

ANDAs for valsartan that were initially filed or held by multiple predecessor entities that had owned or operated the Malta facility, including Forest Laboratories, Ivax Pharmaceuticals, Cobalt Pharmaceuticals, Watson Laboratories, and/or Actavis Generics. Clearly, this facility's purchase of valsartan API, its testing of that incoming API, and its manufacture, testing, and sale of valsartan finished dose is directly relevant.

The basis for Teva's objection to discovery of the Malta facility is that a predecessor entity, Arrow Pharmaceuticals, has been dissolved and thus has not been formally served. Ex. 16, Teva Ltr. to Counsel. Teva's suggestion that it does not sufficiently own or control the Malta facility is specious at best. Teva's own website indicates that the company acquired Actavis Generics in August 2016, and along with it, the Malta facility. Ex. 17, Teva Website. Teva employees, including those affirmatively identified as document custodians in this case, frequently communicated with the FDA regarding recall of valsartan finished dose product manufactured at the Malta facility, and provided the FDA with documents and information obtained from the Malta Arrow Facility. Ex. 18, TEVA-MDL2875-00004051. Documents also indicate that the valsartan finished dose products were shipped directly from the Malta facility to a Teva entity in the United States for distribution and sale. *Id.* In terms of Teva's "control" over the Malta facility or its records, the same Teva employee that interfaced with the FDA about the recall was able to query data at the Malta facility. Ex. 19, TEVA-MDL2875-00005759. Furthermore, the facility's "elemental impurity risk analysis" of valsartan was conducted in 2017 – and was obviously undertaken at Teva's behest. Ex. 20, TEVA-MDL2875-00001350 (excerpt of confidential document agreed upon by the Parties).

Simply put, Teva cannot carve-out the Malta facility from discovery.

ii. Other Downstream Facilities

Discovery should also include other downstream facilities besides API and finished dose manufacturing facilities, such as facilities that bottled, repackaged, or labeled valsartan finished dose.

Just as valsartan API and finished dose manufacturers are under affirmative obligations to comply with cGMPs, so too are all entities involved in the bottling and labeling of finished dose valsartan products. These obligations include many of the same obligations required of the drug manufacturers (such as the establishment of a quality control department, as discussed *supra* at II.a.), but also include specific obligations related to the distribution and identification of the drug, which are clearly relevant to not only the personal injury claims, but also the economic loss claims. These obligations include: an obligation to provide documentation sufficient to identify every drug product and the history of the manufacture and control of the batch (*see* 21 CFR § 211.130); as well as an obligation to affirmatively update batch production or control records with results of examinations of packaged and labeled products (*see* 21 CFR § 211.134). Bottling and labeling facilities also have obligations to ensure that no adulterated or contaminated products enter or are distributed in the United States under the DSCSA.

In order to assess Defendants' compliance with their federal obligations at every step of the manufacturing process, Plaintiffs are entitled to discovery of these downstream facilities. This would include discovery regarding inspections (because each and every one of these facilities had regulatory obligations to comply with, including compliance with cGMPs), discovery regarding their quality assurance divisions, practices, procedures and controls (because each and every one of these facilities had regulatory obligations to establish quality assurance

controls), and also discovery regarding any testing performed at or obtained for use in their part of the process (because each and every one of these facilities had obligations under both the 21 CFR § 211 *et seq.,* and also the DSCSA). Indeed, confirming compliance with their regulatory obligations is the reason why the FDA inspected Hetero USA and Prinston, even though they do not actually physically manufacture drug products. *See* Exs. 6, 7.

III. Plaintiffs Are Entitled to Discovery Regarding Other Products Using the Same Manufacturing Processes, and Solvents as Those for Valsartan API

Plaintiffs seek discovery of (i) the manufacturing processes, solvents, and testing Defendants used to make other sartan drugs, (ii) any nitrosamine or carcinogenic impurity discovered related to any of these drugs, and (iii) other manufacturing processes which use the same recycled solvents or catalysts.

There is no dispute that "discovery of similar, if not identical, models is routinely permitted in product liability cases." *Culligan v. Yamaha Motor Corp.*, 110 F.R.D. 122, 126 (S.D.N.Y. 1986).

Moreover, and most pertinent to the facts at issue here, courts have allowed discovery of information regarding the same component part in a different product in a number of product defect cases. *See, e.g.*, *Fine v. Facet Aerospace Products Co.,* 133 F.R.D. 439, 441 (S.D.N.Y.1990) ("Generally, different models of a product will be relevant if they share….those characteristics pertinent to the legal issues raised in the litigation."); *Schaap v. Executive Industries, Inc.,* 130 F.R.D. 384, 387 (N.D.Ill.1990) (holding information concerning similar models that have the same component parts to be discoverable); *Bowman v. General Motors Corp.,* 64 F.R.D. 62, 70–71 (E.D.Pa.1974) (allowing discovery of information about subsequent

vehicle model with similar fuel system); *Uitts v. General Motors Corp.,* 58 F.R.D. 450, 451 (E.D.Pa.1972) (allowing discovery of all information relating to similar accidents in vehicles manufactured by defendant with a spring identical to the one at issue).

Discovery regarding i) the manufacturing processes, solvents, and testing Defendants utilized during the manufacture of other sartan drugs, ii) any nitrosamine or carcinogenic impurity discovered related to any of these drugs, and iii) other manufacturing processes which use the same recycled solvents or catalysts, bears directly upon the issue of whether Defendants were on notice of the defect in their products. Such discovery "involving similar products is relevant in products liability cases to show notice to defendants of the danger and cause of the accident." *In re Aircrash Disaster Near Roselawn, Ind., Oct., 31.1994,* 172 F.R.D. 295, 306 (N.D.Ill.1997); *accord Nachtsheim v. Beech Aircraft Corp.*, 847 F.2d 1261, 1268 (7th Cir.1988); *Josephs v. Harris Corp*., 677 F.2d 985 (3d Cir.1982) (finding that discovery regarding similar printing presses was relevant to the issue of duty to warn and existence of defect, and was therefore discoverable in a products liability action).

Additionally, at issue in this litigation are the manufacturing process changes made by the Defendants to their valsartan manufacturing processes *over time*. Plaintiffs must be afforded the opportunity to fully understand the full chronology of the manufacturing changes (including where the process began) with respect to the valsartan process. A critical and necessary piece of this analysis is understanding the manufacturing changes made by the Defendants to the other nearly identical sartans as well. *See, e.g., Bayer AG v. Sony Elecs., Inc.*, 202 F.R.D. 404, 408 (D. Del. 2001) ("…Plaintiff cannot be expected to identify which [manufacturing] changes it deems

relevant without first having an opportunity to examine all of these "innumerable" changes. As a result, the Court finds the scope of Plaintiff's request to be warranted").

a. The Manufacturing Practices Regarding Valsartan, Losartan, Irbesartan, Olmesartan and Candesartan Are Substantially Similar

Valsartan belongs to a class of drugs classified as Angiotensin-II receptor antagonists, colloquially called "sartans." A subsection of these sartans (including Valsartan, Losartan, Irbesartan, Olmesartan and Candesartan) require the creation of a specific chemical structure called a tetrazole ring.[8] Regulatory bodies (including the FDA, and EMA) have identified that it is this specific process – the creation of the tetrazole ring – and the specific manufacturing choices the Defendants made during this process to increase yield and reduce costs, which is the likely root cause of the contamination. *Id*. A toxicology assessment prepared for Defendant Aurobindo additionally confirms the similar structure of these five drugs. Ex. 21, Auro-MDL 2875-0020989 at 3 ("Like Valsartan [irbesartan, candesartan, losartan, and olmesartan] have a specific ring structure (tetrazole) whose synthesis could potentially lead to the formation of impurities such as NDEA"). The similarity between the chemical structures of these drugs is the reason why all the world regulatory bodies proceeded to investigate and study *all* the sartans in the wake of the identification of contamination in Valsartan. *See, e.g.,* FDA ("[w]e are testing samples of other drugs with similar manufacturing processes" including olmesartan and candesartan);[9] EMA ("[t]he review concerns candesartan, irbesartan, losartan, olmesartan and valsartan, which belong to a class of medicines called sartans (also known as angiotensin-II-

[8] https://www.ema.europa.eu/en/documents/referral/valsartan-article-31-referral-sartan-medicines-companies-review-manufacturing-processes-avoid_en.pdf.
[9] https://dcatvci.org/6123-fda-and-ema-broaden-review-of-impurities-in-api-manufacturing.

receptor antagonists)…these sartan medicines have a specific ring structure (tetrazole) whose synthesis could potentially lead to the formation of nitrosamine impurities")[10]; Health Canada ("[t]he five sartan drugs Health Canada is focused on (valsartan, candesartan, irbesartan, losartan, and olmesartan) all share a similar chemical structure.")[11] Additionally, at least one Defendant discovered its valsartan was contaminated only *after* discovering its Losartan was contaminated. Ex. 21, Auro-MDL 2875-0020989 at 3. The regulatory agencies recognized it would be impossible to study any one of these drugs without obvious and real implications to the other four drugs. The regulatory agencies also recognized that investigation into only some of these drugs would lead to an incomplete analysis of the total contamination, and its root causes.

i. All Defendants Manufacture Many (If Not All) of these Sartans

Were this not enough, every single manufacturing is engaged in the API manufacturing of these additional sartans. This includes ZHP (which manufactures all 5), Hetero Labs (which manufactures all 5), Mylan (which manufactures valsartan, candesartan and olmesartan), and Aurobindo (which manufactures valsartan, olmesartan, and losartan).[12] Several of the finished dose manufacturers in the valsartan litigation, who did not manufacture their own valsartan API (and disclaim any independent knowledge of the API manufacturing process for valsartan), were simultaneously manufacturing their own tetrazole ring sartan APIs. For example, Teva

[10] https://www.ema.europa.eu/en/documents/referral/valsartan-article-31-referral-sartan-medicines-companies-review-manufacturing-processes-avoid_en.pdf.
[11] https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2018/68620a-eng.php.
[12] http://en.huahaipharm.com/ylzjy/index.aspx; https://www.pharmacompass.com/apis-products/hetero-drugs-limited; https://www.pharmacompass.com/apis-products/hetero-drugs-limited; https://www.mylan.com/en/productsearch; https://www.aurobindousa.com/product-catalog/.

manufactures API for candesartan, irbesartan, and Olmesartan, and Torrent manufactures API for candesartan and olmesartan.[13]

In situations where a Defendant makes a variety of products, but where only one of those products is alleged to have caused injury in the instant action, Courts routinely compel discovery regarding the not-at-issue products. Courts have found that discovery was appropriate for other products "not at issue" especially if they were manufactured in the same plant (as appears to have occurred here). *See, e.g., McKellips v. Kumho Tire Co.*, 305 F.R.D. 655, 677 (D. Kan. 2015) (finding that discovery was permissible for similar tires manufactured at the same factory in Vietnam).

To the extent that Finished Dose manufacturers appear prepared to argue that they are not liable for the manufacturing changes implemented by the API manufacturers and were not on notice of a potential issue with the process, their own manufacturing processes are central. Documents regarding whether these finished dose manufacturers were observing and/or analyzing potential harbingers of impurities resulting from the same or similar API manufacturing practices are clearly relevant to the analysis.

ii. These Sartans All Contain Similar Potential for Nitrosamine Formation

Beyond their obvious chemical structure similarities, the other sartans appear to all have similar potential for nitrosamine formation during their manufacture. This further supports the need to include these drugs in the scope of discovery. This is for multiple reasons, including

[13] https://www.tapi.com/productcatalogtapi.pdf; https://www.pharmacompass.com/apis-products/torrent-pharmaceuticals-limited.

those discussed above, and may go directly to the question of when the Defendants should have been on notice that their drugs were contaminated.

However, in their Responses and Objections to Plaintiffs RFPDs, Defendants take the position that the *only* impurities at issue in this case are NDMA and NDEA. Ex. 2, Mylan's Objs. to RFPDs at 37-38 (objecting to requests for academic studies to the extent they are "not limited to studies or analysis pertaining to Valsartan API containing NDMA or NDEA impurities"). This is not reasonable. At the time of the JPML's transfer order, the only carcinogenic nitrosamine contaminants known to be present in the valsartan drugs were NDMA and NDEA. Subsequent independent laboratory testing has confirmed that at least one other carcinogenic substance, a solvent known as DMF (dimethylformamide), which was used in the valsartan manufacturing process, has been detected in finished dose pills sourced from Aurobindo. Ex. 22, Valisure Citizen Petition at 5. Moreover, other related sartans have tested positive for similar carcinogenic contaminants; e.g., losartan distributed by Torrent has been recalled due to NMBA contamination.[14]

The ultimate extent of the Defendants' liability remains to be established through discovery. The question of whether Defendants observed any unknown impurity in any of their substantially similar sartan manufacturing processes, and when they were discovered, bears directly on the issue of whether and when they were on notice of contaminants in their products.

[14] https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-0.

b. Discovery Regarding Other Processes Which Utilize Recycled or Recovered Solvents Should Be Permitted

Plaintiffs should be afforded discovery regarding other manufacturing processes that utilize the same solvents used in valsartan. At issue in this case is to what extent the process used to recover solvents (which were then used in subsequent valsartan manufacturing processes) may have led to the contamination. In a Warning Letter sent to Lantech Pharmaceuticals, a solvent recovery processing company in India, the FDA found that Lantech was notified by a customer that they were providing solvent that contained NDEA. Ex. 23, August 8, 2019, Lantech Warning Letter ¶ 1. The letter further went on to describe a failure to "implement a procedure for investigating unknown peaks in recovered solvent chromatograms observed during analytical testing." *Id*. Aurobindo, one such customer of Lantech Pharmaceuticals, confirmed Lantech's role in the contamination of their products. Ex. 24, Auro-MDL2875-0020775 (finding that the root cause of NDEA impurities "is due to Recovered Tri N Butyl Tin Chloride manufactured at contract manufacturing unit 'Lantech Pharmaceutical Ltd.'"). Discovery regarding the use of recovered solvents from Lantech assists Plaintiffs in understanding the scope and extent of the contamination, and understanding when Defendant Aurobindo (or any other Defendant who may have utilized Lantech) was on notice that there might be a contamination.

Some Defendants also utilized Dimethylformamide ("DMF") in their manufacturing processes. DMF is a Class 2 Solvent. *See* Ex. 22, Valisure Citizen Petition at 2. Valisure, an online pharmacy that filed a Citizen's Petition to the FDA, argued that utilization of DMF as a solvent "should be limited in pharmaceutical products because of their inherent toxicity." *Id*. DMF has also been listed as a cancer causing chemical by the State of California for the

purposes of Proposition 65. *Id.* at 3. Indeed, the California Environmental Protection Agency expressed concern regarding the potential genotoxicity and permeation enhancing activity of DMF whereby it "may act as an escort to facilitate the easy entry of either endogenous or exogenous carcinogen." *Id.* at 4. And yet, this was the choice of solvent some of these manufacturers had made, or were contemplating making, with respect to their valsartan products. Given this inherent toxicity, Plaintiffs are entitled to discovery about what risk assessments were conducted prior to making the decision to use DMF in any drug manufacturing process, not just the sartan processes.

Because the solvent itself may have presented evidence of contamination in testing, Plaintiffs are entitled to discovery regarding other drug manufacturing process that used the same at-issue solvent, in part to determine if impurity tests of those drugs were presenting aberrant out-of-specification results, and whether Defendants conducted adequate risk assessments for the use of those solvents in drug product manufacture.

c. Defendants' Core Discovery Production Demonstrates the Need for an Expanded Scope of Discovery Beyond Just Valsartan

It is clear that the other sartans are often discussed, analyzed, and tested simultaneously and interchangeably (by both world health regulators (*supra* at III.a), and the *Defendants themselves*) because of their obvious chemical similarity and impurity-generating potential. Yet, the Defendants are seeking a sweeping shield to prevent discovery into obviously relevant information.

Indeed, in their Core Discovery production, the Defendants have already begun the process of redacting out other "irrelevant" sartan drugs[15] and other solvents used in the manufacture of those allegedly "irrelevant" drugs (including, possibly, the same solvents as at issue here). These redactions have rendered many Core Discovery documents (including correspondence with the FDA regarding meetings about the valsartan recall) almost useless.

For example, much of Hetero's communication with the FDA regarding the very recall at issue in this litigation has been redacted entirely. This includes redacting (in their entirety) 19 individual attachments, which were sent to the FDA in advance of a meeting about the recall. Ex. 25, HETERO000028977 (Plaintiffs only cite this document by bates references as is required by the Protective Order (D.E. 136)).[16]

If the Court were to arbitrarily limit discovery to only valsartan, this practice would only continue and mushroom, which will hamper the effort to answer the questions of what happened

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[15] At a minimum, the Court should require the Defendants to re-produce their Core Discovery without redaction. This is especially so for those redacted documents which are correspondence with the FDA. Indeed, Courts disfavor redactions on the basis of so-called "responsiveness" such as those Defendants' have applied to their documents regarding inspections and recalls. For one, the practice of redacting for nonresponsiveness or irrelevance finds no explicit support in the Federal Rules of Civil Procedure, and the only bases for prohibiting a party from seeing a portion of a document in the Rules are claims of privilege or work-product protection. Fed. R. Civ. P. 26(b)(5); *see* Steven J. Purcell, *Document Production in Federal Litigation: Can You Redact for Nonresponsiveness*?, 59–Dec. Fed. Law. 22 (Dec.2012) (discussing lack of support for nonresponsiveness redactions in the Federal Rules of Civil Procedure).

[16] Plaintiffs sought to append a non-confidential, excerpted version of this document to the brief to illustrate Defendants' use of redactions with respect to other sartan drugs in communication documents with the FDA. However, Counsel for Hetero USA requested even further redaction (to redact out the name of the other non-valsartan drug, which Hetero USA claims they "inadvertently" overlooked). As such, the Parties did not come to an agreement on a non-confidential document to attach. In lieu of the confidential document, Plaintiffs include the correspondence between the Parties. However, the fact that there is even a dispute as to whether Plaintiffs are entitled to know the *mere names* of other drugs being discussed with the FDA simultaneously as valsartan further demonstrates the need for an expanded scope of discovery.

and why. In making redactions regarding other sartans and/or solvents used in manufacturing the other sartans, Defendants are seizing the opportunity to improperly "unilaterally decide that information within a discoverable document need not be disclosed to their opponents." *Burris v. Versa Prod., Inc.,* 2013 WL 608742, at *3 (D. Minn. Feb. 19, 2013) (Ex. 26). This outcome consequently deprives Plaintiffs of "the opportunity to see information in its full context and fueling mistrust about the redactions' propriety." *Id.* This should not be permitted here.

Defendants will undoubtedly continue to utilize an order denying discovery into other sartans as a vehicle by which to hide the ball. For example, in a critical 2017 inspection of a ZHP facility, the inspector noticed discrepancies in analytical testing for valsartan, and two other products, which have been redacted. Ex. 27, Excerpt of 2017 Establishment Inspection Report, PRINSTONOO74160 (excerpt of confidential document agreed upon by the Parties). The report further goes on to discuss unidentified peaks seen in Liquid Chromatography for a drug, which ZHP has redacted. *Id.* Defendant ZHP's redactions to this key document seriously hamper Plaintiffs' ability to analyze the totality of the FDA's findings, because Plaintiffs do not know what other API processes the FDA was inspecting concomitantly with valsartan.

IV. Defendants' Litigation Hold Notices Should Be Produced.

The law requires a potential litigant to preserve potential relevant evidence as soon as litigation is a reasonable possibility. *Bagley v. Yale Univ.*, 318 F.R.D. 234, 237 (D. Conn. 2016). This is a legal requirement. This Court recognized this in the initial Case Management Order directing: "All parties and their counsel are reminded of their duty to take reasonable measures to preserve documents and electronically stored information and data that are potentially relevant." (D.E. 5). Thus, the notice itself, as well as the dates, distribution lists, and preservation

instructions in a litigation hold, cannot be shielded from discovery. This information will allow Plaintiffs to knowledgeably approach the question of whether relevant evidence was preserved, and to understand the full scope of potential custodians. Instructively, in *Benicar*, the defendants voluntarily produced their unredacted litigation hold and its recipients to assist the plaintiffs in identifying the proper custodians in the case. (Ex. 29). Even more importantly for this case, some defendants are outsourcing communications with the FDA to independent consultants and non-employees. As such, Plaintiffs are entitled to know if these outside consultants/entities have been instructed not to destroy communications.

Plaintiffs anticipate that Defendants will claim the litigation hold notices are privileged, assuming they were written by attorneys and contain actual legal advice. As a threshold matter, "[t]he party asserting privilege bears the burden of demonstrating that it applies." *United States v. Halliburton Co.*, 74 F. Supp. 3d 183, 187 (D.D.C. 2014). Because privileges are a "derogation of the truth-seeking process," courts construe them strictly and narrowly. *Id.* The attorney-client privilege shelters only "confidential communications between an attorney and client, including their agents, made with a primary purpose of seeking or providing legal advice." *Id.* Litigation hold notices contain instructions required by law to be disseminated, and not legal advice. Courts have recognized that "the predominant purpose of [a litigation hold is] to give recipients forceful instructions about what they must do, rather than advice about what they might do." *Bagley*, 318 F.R.D. at 240. Preventing their disclosure, especially when they are widely disseminated, as they should be, does not further the purposes of the attorney-client privilege and only results in the degradation of the law's truth-seeking function. *Id.*; *Halliburton*, 74 F. Supp. 3d at 190-91. Moreover, to the extent the Defendants can make a showing that any portion of a litigation hold

notice contains privileged information, substantive legal advice beyond the document preservation instructions can otherwise be redacted.

The work-product privilege does not protect litigation holds either. *Id.* at 191. Litigation holds are "simply not the type of preparation that is intended to be protected by the privilege, especially given today's liberal standards for conducting discovery where companies have a duty to preserve electronic documents." *Halliburton*, 74 F. Supp. 3d at 192. "An attorney cannot complain that his preparations for trial have been unfairly affected by his opponent receiving information about document retention practices to which he is entitled." *Id.*

Litigation holds have been produced in other MDL litigation as well. For example, in *In re Ethicon, Inc. Pelvic Repair Systems Product Liability Litigation*, 299 F.R.D. 502 (S.D.W.V. 2014), the pelvic mesh MDL Court discussed the timing and contents of the litigation holds produced by Johnson & Johnson/Ethicon in ruling on plaintiffs' motion for spoliation sanctions, which was granted in part. As already noted, the defendants voluntarily produced their unredacted litigation hold and its recipients in *Benicar*. (Ex. 29).

Plaintiffs recognize that this Court has indicated that the disclosure of litigation holds should occur in the setting of allegations of spoliation. *Major Tours, Inc. v. Colorel*, 2009 WL 2413631 (D.N.J. Aug. 4, 2009) (Ex. 30). In that case, the parties primarily litigated whether spoliation occurred and not whether a privilege applied in the first place, so the issue here is different. *Id.* As described above, the weight of authority supports production of the litigation holds, dissemination dates, and distribution lists, and there is no requirement that this only occur after evidence of spoliation is discovered – in fact it is the contents of the litigation holds that often demonstrate the failure to preserve potential evidence.

Moreover, there is evidence of potential spoliation in this litigation, even at this early stage. For example, a 2016 FDA inspection report of Hetero Labs Limited states that:

> (a) A document shredder was introduced into your firm's "DOCUMENTS STORAGE AREA" on December 03, 2016 at 15:44, approximately 4 days prior to the current US FDA inspection.
>
> (b) After introduction of the document shredder we observed extensive shredding of what appears to be controlled documents and extensive signing of documents by QA. These documents were of a color consistent with batch packaging records and batch manufacturing records, among other documents. Your firm failed to maintain documentation of what had been shredded.
>
> (c) On December 06, 2016, as we observed that a contract employee with QA removed documents from the shredder and placed them in his pocket.
>
> (d) On December 07, 2016, at approximately 1:13 (in the middle of the night) individuals were shredding documents. Your firm stated this event represented cleaning staff shredding documents.
>
> (e) Other anomalous events were observed associated with~ shredder. Your firm failed to clarify the correlation of introducing the shredder to the "DOCUMENTS. STQRAGE AREA" prior to the current US.FDA inspection.

Ex. 31, 2016 Form 483 for Hetero Labs Ltd. Not surprisingly, Hetero could not explain these observations. *Id.* at 2. The inspector also found other "controlled documents" in the facility's "scrap area" and other ones "in shred bins, shredders and trash bins." *Id.* at 2-3. Hetero's Quality Control Manager admitted that "QC documents are shredded in QA without a corresponding log for documentation." *Id.* at 3.

The FDA has identified similar concerning conduct at Mylan's facilities:

> Your quality unit failed to monitor and investigate error signals generated by the computerized systems that you use for high

> performance liquid chromatography and gas chromatography. These signals indicated the loss or deletion of original CGMP analytical data. However, your quality unit did not comprehensively address the error signals or determine the scope or impact of lost or deleted data until after these problems were reviewed during our inspection.
>
> For example, our investigator reviewed audit trails from August 2016 assay testing on **(b)(4)** batch **(b)(4)** and dissolution testing for **(b)(4)** tablets batch **(b)(4)**. *The audit trail for these tests included the message, "deleted result set," but neither of these two incidents were recorded in the analytical packages for these batches of drug products, nor were they reviewed or investigated by the quality unit.*
>
> In addition, during the inspection, our investigator observed that your Empower 3 system audit trail displayed many instances of a "Project Integrity Failed" message, which indicates that injections were missing from the results of analytical testing. For example, in **(b)(4)** analysis for **(b)(4)** tablets batch **(b)(4)** conducted on June 20, 2016, no chromatogram was rendered for the initial run of testing. The data package for this testing clearly shows that the initial run is missing, but your quality unit did not investigate the incident.[17]

In fact, this Court has recognized the importance of providing this information, and ordered production of key information even without production of the actual hold letters: "[P]laintiffs are entitled to know which categories of electronic storage information employees were instructed to preserve and collect, and what specific actions they were instructed to undertake to that end." *Major Tours*, 2009 WL 2413631, at *2. To this end, other courts have also ordered production of the key fundamental information. *See, e.g.*, *Colonial BancGroup Inc. v. PriceWaterhouseCoopers LLP*, 2016 WL 9687001, at *4-5 (M.D. Ala. Jan. 22, 2016) (Ex. 33) (ordering the disclosure of the dates and recipients of the holds, the types of documents and files

[17] (Italics added), Ex. 32, 2017 Mylan Nashik Warning Letter.

subject to the holds, the actions undertaken pursuant to the holds, efforts to enforce the holds, and "any additional, non-duplicative, information concerning its collection, retention and production methods in this case"). As stated by another Court:

> **[P]laintiffs seek answers concerning what has actually happened in this case, i.e., when and to whom the litigation hold letter was given, what kinds and categories of ESI were included in defendants' litigation hold letter, and what specific actions defendants' employees were instructed to take to that end. Although the letters themselves may be privileged, the basic details surrounding the litigation hold are not.** These requests are reasonable and may ultimately benefit defendants if questions ever arise concerning defendants[']' efforts to preserve relevant ESI.

Cannata v. Wyndham Worldwide Corp., 2011 WL 3495987, at *3 (D. Nev. Aug. 10, 2011) (Ex. 34). The litigation hold notices should be disclosed here, especially where there are foreign entities that may not have complied with their obligations under United States law. At the very least, Defendants should be compelled to produce all of the substantive information needed by the Plaintiffs to assess whether preservation obligations were fulfilled, and to have the full distribution lists to compare to the custodian lists.

Respectfully,

ADAM M. SLATER

AMS/lat